PATENT
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1 of 3
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10/22/02

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Applicant: Joseph P. Steiner, et al.

Title: Small Molecule Pipecolic Acid Derivative Hair Growth Compositions and Uses

Appl. No.: 09/784,174

Filing Date: February 16, 2001

Examiner: Rebecca Cook

Art Unit: 1614

Commissioner for Patents
Washington, DC 20231

Sir:

APPEAL BRIEF UNDER 37 C.F.R. § 1.192

This brief answers the final Office Action of February 14, 2002. It is filed with two additional copies of the originally signed brief. It is accompanied by the small entity fee of $160.00 under 37 C.F.R. § 1.17(c). It is timely, since it is filed within four months of the Notice of Appeal dated June 12, 2002, and accompanied by a Petition for an Extension of Time and the fee of $200.00 under 37 C.F.R. § 1.17(a)(2).

I. Real Party Interest

GPI NIL Holdings, Inc. is the real party in interest.

II. Related Appeals and Interferences

The following cases may be related to the present case: (1) Application No. 09/879,888, filed June 14, 2001; and (2) Application No. 09/781,427, filed February 13, 2001. The appeal numbers have yet to be assigned.

III. Status Of Claims

Claims 5-6 and 8 are pending. Claims 1-4 and 7 are cancelled. Claims 5-6 and 8 are appealed.

IV. Status Of Amendments

All amendments were entered.

V. Summary Of Invention

The invention includes a composition comprising an effective amount of a specified compound, a second hair revitalizing agent, and a pharmaceutically acceptable carrier. Specification, p. 4, ll. 14-19; claim 5 (once amended).

VI. Issues

There is one issue presented for review:

A. whether claims 5-6 and 8 are patentable under the judicially created doctrine of obviousness-type double patenting in view of claims 17-32 of copending Application No. 09/879,888.

VII. Grouping Of Claims

For the purpose of this appeal only, the claims stand or fall together for each ground of rejection which Appellant contests and which applies to a group of two or more claims.

VIII. Argument

A. The rejection of claims 5-6 and 8 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 17-32 of copending U.S. Application No. 09/879,888 is improper and should be reversed, because the evidence and explanation of record fail to support the rejection.

A factual finding that is material to patentability can neither stand if it is supported only by conclusory statements nor be resolved only on the subjective belief of an examiner. In re Lee, 277 F.3d 1338, 1346, 61 USPQ2d 1430, 1433 (Fed. Cir. 2002). More particularly, under the facts relevant to this rejection, the grounds for rejection should make two findings clear: (1) the differences between the claims of the '888 application and the species that the Examiner proposed to obtain; and (2) the reasons for choosing that species. MPEP § 804 II. B. 1. The differences were never even summarized in the record. Office Action of 2/14/2, p. 2, ll. 19-22; Office Action of 9/17/1, p. 3, l. 27-p. 4, l. 5. Furthermore, overlap and double patenting are two contrasting issues. MPEP §804 II. ("Domination" is analogous to overlap.). One set of claims overlaps a second set if the first set has a broad claim which encompasses an invention of the second set. Id. Overlap itself, however, cannot support a double patenting rejection. Id. Thus, this rejection is improper and should be reversed, as it is based on a mere conclusion or subjective belief.

IX. Appendix

An appendix containing a copy of the claims involved in the appeal is attached.

X. Conclusion

The rejection should be reversed and the application allowed.

Respectfully submitted,

Dated: October 15, 2002

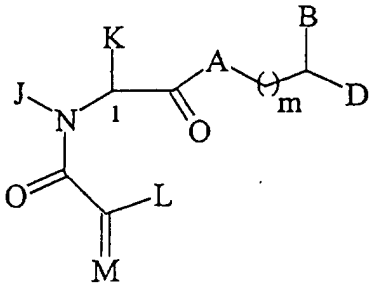
By: _____
Sean A. Passino
Reg. No. 45,943

If any [further] extension of time under 37 C.F.R. § 1.136 is required to obtain entry of this Appeal Brief, such extension is hereby respectfully requested. If there are any fees due under 37 C.F.R. §§ 1.16 or 1.17 which are not enclosed herewith, including any fees required for an extension of time under 37 C.F.R. § 1.136, please charge such fees to our Deposit Account No. 19-0741.

APPENDIX

5. A pharmaceutical composition which comprises:

(i) an effective amount of a compound for treating alopecia or promoting hair growth in an animal in need thereof, wherein said compound is of formula I



I

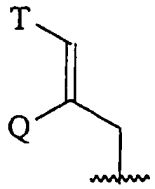
or a pharmaceutically acceptable salt, ester, or solvate thereof, wherein:

A is O, NH, or N-(C_1-C_4 alkyl);

B and D are independently Ar, C_5-C_7 cycloalkyl substituted C_1-C_6 straight or branched chain alkyl or C_2-C_6 straight or branched chain alkenyl, C_5-C_7 cycloalkenyl substituted C_1-C_6 straight or branched chain alkyl or C_2-C_6 straight or branched chain alkenyl, or Ar substituted C_1-C_6 straight or branched chain alkyl or C_2-C_6 straight or branched chain alkenyl,

wherein in each case, one or two carbon atom(s) of said alkyl or alkenyl is/are optionally substituted with one or two heteroatom(s) independently selected from the group consisting of oxygen, sulfur, SO, and SO_2,

or B and D are independently the fragment



wherein Q is hydrogen, C_1-C_6 straight or branched chain alkyl or C_2-C_6 straight or branched chain alkenyl; and

T is Ar or C_5-C_7 cycloalkyl substituted at positions 3 and 4 with substituents independently selected from the group consisting of hydrogen, hydroxy, O-(C_1-C_4 alkyl), O-(C_2-C_4 alkenyl), and carbonyl;

Ar is selected from the group consisting of 1-napthyl, 2-napthyl, 2-furyl, 3-furyl, 2-thienyl, 3-thienyl, 2-pyridyl, 3- pyridyl, 4-pyridyl and phenyl, monocyclic and bicyclic heterocyclic ring systems with individual ring sizes being 5 or 6 which have in either or both rings a total of 1-4 heteroatoms independently selected from oxygen, nitrogen and sulfur,

wherein Ar has 1-3 substituent(s) independently selected from the group consisting of hydrogen, halo, hydroxy, hydroxymethyl, nitro, CF_3, trifluoromethoxy, C_1-C_6 straight or branched chain alkyl, C_2-C_6 straight or branched chain alkenyl, O-(C_1-C_4 straight or branched chain alkyl), O-(C_2-C_4 straight or branched chain alkenyl), O-benzyl, O-phenyl, amino, 1,2- methylenedioxy, carbonyl, and phenyl;

L is either hydrogen or U; M is either oxygen or CH-U, provided that if L is hydrogen, then M is CH-U, or if M is oxygen then L is U;

U is hydrogen, O-(C_1-C_4 straight or branched chain alkyl), O-(C_2-C_4 straight or branched chain alkenyl), C_1-C_6 straight or branched chain alkyl, C_2-C_6 straight or branched chain alkenyl, C_5-C_7 cycloalkyl, C_5-C_7 cycloalkenyl substituted with C_1-C_4

straight or branched chain alkyl or C_2-C_4 straight or branched chain alkenyl, (C_1-C_4 alkyl or C_2-C_4 alkenyl)-Ar, or Ar;

J is hydrogen, C_1 or C_2 alkyl, or benzyl; K is C_1-C_4 straight or branched chain alkyl, benzyl or cyclohexylmethyl; or J and K are taken together to form a 7 membered heterocyclic ring which is substituted with oxygen, sulfur, SO, or SO_2;

m is 0-3; and

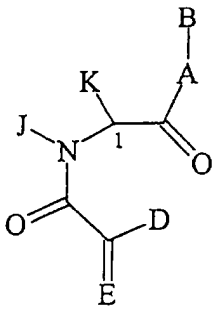
said compound has an affinity for FKBP-type immunophilins;

(ii) a second hair revitalizing agent; and

(iii) a pharmaceutically acceptable carrier.

6. A pharmaceutical composition which comprises:

(i) an effective amount of a compound for treating alopecia or promoting hair growth in an animal in need thereof, wherein said compound is of formula II

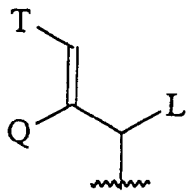


II

or a pharmaceutically acceptable salt, ester, or solvate thereof, wherein:

A is O, NH, or N-(C_1-C_4 alkyl);

B is hydrogen, CHL-Ar, C_1-C_6 straight or branched chain alkyl, C_2-C_6 straight or branched chain alkenyl, C_5-C_7 cycloalkyl, C_5-C_7 cycloalkenyl, Ar substituted C_1-C_6 alkyl or C_2-C_6 alkenyl, or



wherein L and Q are independently hydrogen, C_1-C_6 straight or branched chain alkyl, or C_2-C_6 straight or branched chain alkenyl; and

T is Ar or C_5-C_7 cyclohexyl substituted at positions 3 and 4 with substituents independently selected from the group consisting of hydrogen, hydroxy, O-(C_1-C_4 alkyl), O-(C_2-C_4 alkenyl), and carbonyl;

Ar is selected from the group consisting of 1-napthyl, 2-napthyl, 2-furyl, 3-furyl, 2-thienyl, 2-pyridyl, 3-pyridyl, 4-pyridyl, and phenyl, having 1-3 substituent(s) independently selected from the group consisting of hydrogen, halo, hydroxy, nitro, CF_3, C_1-C_6 straight or branched chain alkyl, C_2-C_6 straight or branched chain alkenyl, O-(C_1-C_4 straight or branched chain alkyl), O-(C_2-C_4 straight or branched chain alkenyl), O-benzyl, O-phenyl, amino, and phenyl;

D is hydrogen or U; E is oxygen or CH-U, provided that if D is hydrogen, then E is CH-U, or if E is oxygen, then D is U;

U is hydrogen, O-(C_1-C_4 straight or branched chain alkyl), O-(C_2-C_4 straight or branched chain alkenyl), C_1-C_6 straight or branched chain alkyl, C_2-C_6 straight or branched chain alkenyl, C_5-C_7-cycloalkyl, C_5-C_7 cycloalkenyl substituted with C_1-C_4 straight or branched chain alkyl or C_2-C_4 straight or branched chain alkenyl, 2-indolyl, 3-indolyl, (C_1-C_4 alkyl or C_2-C_4 alkenyl)-Ar, or Ar;

J is hydrogen, C_1 or C_2 alkyl, or benzyl; K is C_1-C_4 straight or branched chain alkyl, benzyl or cyclohexylethyl; or J and K are taken together to form a 7 membered heterocyclic ring which is substituted with oxygen, sulfur, SO, or SO_2; and

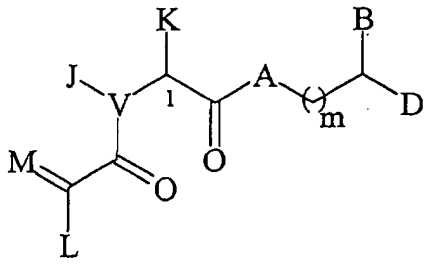
said compound has an affinity for FKBP-type immunophilins;

(ii) a second hair revitalizing agent; and

(iii) a pharmaceutically acceptable carrier.

8. A pharmaceutical composition which comprises:

(i) an effective amount of a compound for treating alopecia or promoting hair growth in an animal in need thereof, wherein said compound is of formula IV



IV

or a pharmaceutically acceptable salt, ester, or solvate thereof, wherein:

V is C, N, or S;

J and K, taken together with V and the carbon atom to which they are respectively attached, form a 7 membered saturated or unsaturated heterocyclic ring having, in addition to V, one or more heteroatom(s) selected from the group consisting of O, S, SO, SO_2, N, NH, and NR;

R is either C_1-C_9 straight or branched chain alkyl, C_2-C_9 straight or branched chain alkenyl, C_3-C_9 cycloalkyl, C_5-C_7 cycloalkenyl, or Ar_1,

wherein R is either unsubstituted of substituted with one or more substituent(s) independently selected from the group consisting of halo, haloalkyl, carbonyl, carboxy, hydroxy, nitro, trifluoromethyl, C_1-C_6 straight or branched chain alkyl, C_2-C_6 straight or branched chain alkenyl, C_1-C_4 alkoxy, C_2-C_4 alkenyloxy, phenoxy, benzyloxy, thioalkyl, alkylthio, sulfhydryl, amino, alkylamino, aminoalkyl, aminocarboxyl, and Ar_2;

Ar_1 and Ar_2 are independently an alicyclic or aromatic, mono-, bi- or tricyclic, carbo- or heterocyclic ring,

wherein the individual ring size is 5-8 members, wherein said heterocyclic ring has 1-6 heteroatom(s) independently selected from the group consisting of O, N, and S;

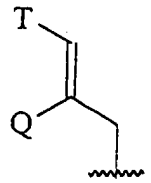
A is O, NH, or N-(C_1-C_4 alkyl);

B and D are independently Ar, C_5-C_7 cycloalkyl substituted C_1-C_6 straight or branched chain alkyl or C_2-C_6 straight or branched chain alkenyl, C_5-C_7 cycloalkenyl substituted C_1-C_6 straight or branched chain alkyl or C_2-C_6 straight or branched chain

alkenyl, or Ar substituted C_1-C_6 straight or branched chain alkyl or C_2-C_6 straight or branched chain alkenyl,

wherein in each case, one or two carbon atom(s) of said alkyl or alkenyl is/are optionally substituted with one or two heteroatom(s) independently selected from the group consisting of oxygen, sulfur, SO, and SO_2,

or B and D are independently the fragment



wherein Q is hydrogen, C_1-C_6 straight or branched chain alkyl or C_2-C_6 straight or branched chain alkenyl; and

T is Ar or C_5-C_7 cycloalkyl substituted at positions 3 and 4 with substituents independently selected from the group consisting of hydrogen, hydroxy, O-(C_1-C_4 alkyl), O-(C_2-C_4 alkenyl), and carbonyl;

Ar is selected from the group consisting of 1-napthyl, 2-napthyl, 2-furyl, 3-furyl, 2-thienyl, 3-thienyl, 2-pyridyl, 3-pyridyl, 4-pyridyl, phenyl, and monocyclic and bicyclic heterocyclic ring systems with individual ring sizes being 5 or 6,

which have in either or both rings a total of 1-4 heteroatoms independently selected from oxygen, nitrogen and sulfur,

wherein Ar has 1-3 substituent(s) independently selected from the group consisting of hydrogen, halo, hydroxy, hydroxymethyl, nitro,

CF_3, trifluoromethoxy, C_1-C_6 straight or branched chain alkyl, C_2-C_6 straight or branched chain alkenyl, O-(C_1-C_4 straight or branched chain alkyl), O-(C_2-C_4 straight or branched chain alkenyl), O-benzyl, O-phenyl, amino, 1,2-methylenedioxy, carbonyl, and phenyl;

L is either hydrogen or U; M is either oxygen or CH-U, provided that if L is hydrogen, then M is CH-U, or if M is oxygen then L is U;

U is hydrogen, O-(C_1-C_4 straight or branched chain alkyl), O-(C_2-C_4 straight or branched chain alkenyl), C_1-C_6 straight or branched chain alkyl, C_2-C_6 straight or branched chain alkenyl, C_5-C_7 cycloalkyl, C_5-C_7 cycloalkenyl substituted with C_1-C_4 straight or branched chain alkyl or C_2-C_4 straight or branched chain alkenyl, (C_1-C_4 alkyl or C_2-C_4 alkenyl)-Ar, or Ar; and

m is 0-3;

(ii) a second hair revitalizing agent; and

(iii) a pharmaceutically acceptable carrier.